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09/847,703	05/01/2001	Mark W. Kroll	A01P1028	6988

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EXAMINER

OROPEZA, FRANCES P

ART UNIT PAPER NUMBER

3762

DATE MAILED: 01/23/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,703

Applicant(s)

KROLL, MARK W.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/2/03 (Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The Applicant's amendment filed 12/2/03 has overcome the rejection of record, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 103

2. Claims 1, 3-7, 16-18, 25-27, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramm (US 5766225) in view of DeCote, Jr. (US 4708142).

Kramm discloses a system and method to sense cardiac signals and electrically stimulate the ventricles.

As to claims 1, 7, 8, 13, 14, 16, 17, 18, 20, 23-26, 29 and 30, capture of cardiac tissue is determined by sensing signals/ voltage differential/ time delay, both inherent and evoked, within an established time interval (abstract; col. 2 @ 39-45; col. 3 @ 14-15; col. 3 @ 44 - col. 4 @ 2; col. 4 @ 48-52). The stimulation is a pacing pulse (abstract).

Kramm incorporates by reference Williams (US 4932407) to teach leads (Kramm - col. 3 @ 4-10).

Williams teaches an endocardial defibrillation system using tip and ring biventricular electrodes that synchronously stimulate and sense cardiac tissue. The stimulation can be a pacing pulse (col. 2 @ 64-68).

As to claims 1, synchronous biventricular stimulation is delivered between right and left ventricular electrodes (figures 1, 2, 5A, 5C; col. 2 @ 45-68; col. 3 @ 21-41; col. 3 @ 63 - col. 4 @ 7; col. 5 @ 1-35 and 56-64; col. 5 @ 65 - col. 6 @ 26;

especially col. 6 @ 5-6 and 18-21).

As to claim 3, polarities are selected to control the waveform (col. 4 @ 41-44).

As to claims 4 and 5, the pulse is biphasic or monophasic (col. 6 @ 54-59).

As to claim 7, bipolar sensing in the right chamber verifies capture (col. 2 @ 63-68).

Williams incorporates by reference Smits (US 4641656) to teach polarity control (Williams - col. 6 @ 14-16).

As to claim 6, Smits teaches delivering a positive pulse to one electrode/ group of electrodes and a negative pulse to the second electrode/ group of electrodes (col. 2 @ 51-57).

As discussed in the previous ten paragraphs of this action, Kramm discloses the claimed invention except for the biventricular pacing pulses having an amplitude sufficient to capture the heart.

DeCote, Jr. teaches pacing pulse application using sufficient pacing energy based on sufficient pulse amplitude for the purpose of reliably stimulating the heart. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a means to deliver a pulse amplitude sufficient to capture the heart in the Kramm system in order to provide an automatic, accurate, repeatable and relatively simple means to ensure reliable cardiac contractions/ capture and to minimize energy usage, based on a minimal sufficient pulse amplitude, hence increasing the useful life of the implanted stimulation device (abstract; col. 1 @ 6-11; col. 2 @ 30-36; col. 8 @ 53-68).

The Applicant's arguments filed 12/2/03 have been fully considered but they are not convincing. The Applicant asserts Kramm/ Williams do not teach a single pacing pulse applied

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biventricularly and verifying capture in both ventricles. The Examiner disagrees. Kramm teaches pacing (abstract) and determining capture in both ventricles/ the heart stimulation points (col. 2 @ 39-43; col. 3 @ 66 – col. 4 @ 2), and Williams teaches cardiac pacing (col. 2 @ 64-68), a single pacing pulse (col. 6 @ 18-22), and a biventricular pulse (figure 5C; col. 5 @ 56-64), hence the instant invention is taught by Kramm and Williams as detailed in the rejection above.

3. Claims 1, 2, 7-9, 11-13, 18, 22, 23 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salo et al. (US 6278894) in view of DeCote, Jr. (US 4708142).

Salo et al. disclose a multi-site stimulator and impedance sensor using right atrial, right ventricular and coronary sinus electrodes that monitors evoked changes in the cardiac tissue to determine capture (abstract; figure 1; col. 1 @ 6-10; col. 2 @ 49-62; col. 3 @ 32-65; col. 4 @ 21-32; col. 4 @ 66 – col. 5 @ 3; col. 5 @ 23-27, 43-53 and 54-65).

A single bi-ventricular pacing pulse is used to synchronously capture in both ventricles (abstract; col. 2 @ 49-56).

As discussed in the previous paragraph of this action, Salo et al. disclose the claimed invention except for the biventricular pacing pulses having an amplitude sufficient to capture the heart.

DeCote, Jr. teaches pacing pulse application using sufficient pacing energy based on sufficient pulse amplitude for the purpose of reliably stimulating the heart. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a means to deliver a pulse amplitude sufficient to capture the heart in the Salo et al. system in order to provide an automatic, accurate, repeatable and relatively simple means to ensure reliable cardiac

contractions/ capture and to minimize energy usage, based on a minimal sufficient pulse amplitude, hence increasing the useful life of the implanted stimulation device (abstract; col. 1 @ 6-11; col. 2 @ 30-36; col. 8 @ 53-68).

The Applicant's arguments filed 12/2/03 have been fully considered but they are not convincing. The Applicant asserts Salo et al. do not teach a pacing pulse applied biventricularly to synchronously capture in both ventricles. The Examiner disagrees. Salo et al. teach biventricular pacing (abstract; col. 2 @ 49-56) using a single pulse (read to be combining the right and left ventricular electrodes 0 col. 2 @ 55) to synchronously capture in both ventricles, hence the instant invention is taught by Salo et al. as detailed in the rejection above.

4. Claims 14-17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salo et al. (US 6278894) in view of DeCote, Jr. (US 4708142). As discussed in paragraph 3 of this action, modified Salo et al. disclose the claimed invention except for defining the stimulation sensing configurations of A) stimulating with first and second left electrodes and sensing with first and second right electrodes, and B) sensing with left atrial and right ventricular electrodes.

Salo et al. teach cardiac diagnosis and therapy using multiple stimulation and sensing configurations for the purpose of maximizing the understanding of cardiac dynamics to enable selection of simulation configurations that optimize cardiac output (col. 3 @ 32-65). This statement provides a clear suggestion that electrodes included in the stimulation pair and in the sensing pair can be modified to optimize the understanding of the cardiac tissue dynamics, hence enabling stimulation that improves cardiac output. The variation in the stimulation and sensing

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configurations is read to include stimulating with first and second left electrodes and sensing with first and second right electrodes, and sensing with left atrial and right ventricular electrodes. The determination of the most appropriate stimulation and sensing configurations by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the cardiac stimulation and monitoring art.

5. Claims 3, 6, 10 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salo et al. (US 6278894) in view of DeCote, Jr. (US 4708142) and further in view of Weinberg et al. (US 5476485). As discussed in paragraph 3 of this action, modified Salo et al. discloses the claimed invention except for varying the polarity of the electrodes during stimulation and sensing.

Weinberg et al. teach cardiac stimulation and sensing using control of the polarity of the electrodes during stimulation and sensing for the purpose of providing directional control for the stimulation and sensing. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used control of the polarity of stimulation and sensing electrodes in the modified Salo et al. system in order to provide additional control of the stimulation and sensing so the cardiac dynamics can be more precisely understood and by optimal stimulation, the cardiac output can be optimized (col. 1 @ 7-13; col. 4 @ 20 – col. 5 @ 25; col. 5 @ 31-40).

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
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1/15/04



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